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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,767	03/11/2000	Eugene de Juan JR.	49.603 (1699 )	5862

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EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/523,767

Applicant(s)

DE JUAN ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/20/00, 3/12/01, 2/6/02, 6/17/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 23-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-21 is/are rejected.
- 7) ☒ Claim(s) 14 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of 1-22 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Specification*

1. The disclosure is objected to because of the following informalities:  
On page 25 line 18, change "grasping portion 305" to --grasping portion 506--.  
On page 25 line 21, change "stylet 305" to --stylet 508--.  
Appropriate correction is required.

### *Drawings*

2. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 202. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 202a. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the

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description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to because the label of Figure 8 should be changed from label "100G" to label --100b--. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. Figures 7A and 7B are objected to because the specification discloses that the device in Figures 7A and 7B should be shaped as a "shoe-horn type of member", however, the device in Figures 7A and 7B does not look like a "shoe-horn type of member".

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitation "shoe-horn type member". The term "type" renders this claim indefinite.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,817,099 to Skolik et al.

Regarding claim 1, Skolik discloses a method for providing access within an eye comprising providing an entry alignment device and inserting the entry alignment device into the eye (see Column 4 lines 15-20).

Regarding claims 2 and 3, Skolik discloses that when the entry alignment device is removed, the entry apertures are self-sealing (see Column 2 lines 32-39).

Regarding claim 4 and 5, Skolik discloses that the method further discloses providing and inserting a surgical instrument, such as an aspirator (see Column 10 lines 1-12), with an operable end that is less than 25 gauge through the entry apertures (see Column 1 lines 41-43).

Regarding claim 6, Skolik discloses that the entry alignment device is in the form of a metal cannula (see Column 5 lines 47-51).

Regarding claim 7, Skolik discloses that a plurality of entry alignment devices may be inserted into the eye (see Column 12 lines 43-45).

Regarding claim 8, Skolik discloses inserting an operable end of a surgical instrument through the entry alignment device (see Column 12 lines 43-45).

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Regarding claim 9, Skolik discloses that the method further comprises providing and inserting an infusion cannula (see Column 10 lines 1-5) with an operable end that is less than 25 gauge (see Column 5 lines 36-43).

Regarding claim 10, Skolik discloses that the method further discloses sealing the apertures without the use of sutures (see Column 2 lines 32-39).

11. Claims 1, 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,676,669 to Colvard. Colvard discloses a method for providing access within an eye comprising providing an entry alignment device (see Column 8 lines 5-13) and inserting the entry alignment device at an angle less than 45 degrees with respect to a normal to the eye (see FIG. 8a cylindrical insertion device 34).

*Claim Rejections - 35 USC § 103*

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 13 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,487,725 to Peyman in view of Skolik et al. '099 and U.S. Patent No. 5,919,158 to Saperstein et al.

Peyman discloses the claimed invention except for the use of the entry alignment devices and the insertion of a light source. Skolik discloses that an entry alignment device should be used in ocular surgery to protect the surrounding tissue from mechanical and thermal injury (see abstract lines 5-7). Therefore, it would have been obvious to one having ordinary skill in the art at the time

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the invention was made to use an entry alignment device in order to protect the surrounding tissue from mechanical and thermal injury. Saperstein teaches the use of a light source to illuminate an area the surgeon is working on (see Column 5 lines 13-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to insert a light source in order to illuminate the area in which the surgeon is working.

Regarding claim 13, Peyman discloses inserting a high-speed vitreous cutting/aspirating instrument and removing vitreous gel using the high-speed vitreous cutting instrument and implementing a corrective procedure for the retina (see Column 4 line 63 – Column 5 line 18).

Regarding claims 15 and 16, Skolik discloses that when the entry alignment device is removed, the entry apertures are self-sealing (see Column 2 lines 32-39).

Regarding claim 17, Skolik discloses that the entry alignment device is in the form of a metal cannula (see Column 5 lines 47-51).

Regarding claim 18, Skolik discloses that the method further comprises providing and inserting an infusion cannula (see Column 10 lines 1-5) with an operable end that is less than 25 gauge (see Column 5 lines 36-43).

Regarding claim 19, Skolik discloses that the method further discloses sealing the apertures without the use of sutures (see Column 2 lines 32-39).

Regarding claims 20 and 21, Peyman discloses that the step of inserting includes inserting the instruments, hence the entry alignment device, at an angle less than 45 degrees with respect to a normal to the eye.

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*Allowable Subject Matter*

14. Claims 14 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Conclusion*

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to surgical procedures within the eye:

U.S. Patent No. 5,547,473 to Peyman

U.S. Patent No. 5,865,831 to Cozean et al.

U.S. Patent No. 4,692,142 to Skolik et al.

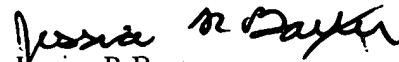
U.S. Patent No. 5,941,250 to Aramant et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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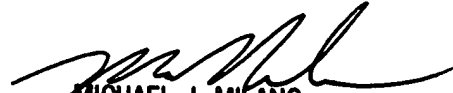
Jessica R Baxter

Examiner

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jrb

July 12, 2002



MICHAEL J. MILANO

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